

DISPOSITION: 9-8-58. Default—destruction.

5704. Meprobamate tablets. (F.D.C. No. 41894. S. Nos. 29-956/7 P.)

QUANTITY: 3 drums containing a total of 512,000 tablets and one drum containing a total of 94,000 tablets at Brooklyn, N.Y.

SHIPPED: A quantity of meprobamate powder was shipped from East Paterson, N.J., and, after its arrival at Brooklyn, N.Y., was tableted and packed into the 3 drums described above. The 1 drum lot was a return shipment which was made on 6-4-58, from Philadelphia, Pa.

LABEL IN PART: (3 drum lot) "2-methyl-2-n-propyl-1, 3-propanediol dicarbamate. For manufacturing, processing, or repacking in the preparation of a new drug limited by Federal law to investigational use. Caution: * * * For Export Only"; (1 drum lot) "100,000 Tablets Meprobamate * * * 400 Mg. * * * Caution * * * Dosage: 1 Tablet 3 times Daily. For investigational and export use only Hall Pharmacal Co., Inc., New York, N.Y."

RESULTS OF INVESTIGATION: Analysis showed that the article (both lots) contained approximately 400 milligrams of meprobamate per tablet.

Investigation showed that the article was not intended for export.

LIBELED: 7-7-58, E. Dist. N.Y.

CHARGE: 502(a)—while held for sale, the statement on the label of the article "For manufacturing, processing, or repacking in the preparation of a new drug limited by Federal law to investigational use * * * For Export Only" was false and misleading; and 505(a)—the article was a new drug, and an application filed pursuant to 505(b) was not effective with respect to such drug.

DISPOSITION: 3-26-59. Consent—destruction.

5705. Meprobamate tablets and meprobamate powder. (F.D.C. No. 41764. S. Nos. 62-771 M, 29-942 P.)

INFORMATION FILED: 9-23-58, Dist. N.J., against Abraham J. Schwartz, Jersey City, N.J.

SHIPPED: *Meprobamate tablets* were shipped on 3-26-57, and *meprobamate powder* was shipped on 3-8-57, from New Jersey to New York.

CHARGE: 502(b)—the articles failed to bear labels containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(e) (1)—the labeling of the articles failed to bear the common or usual name of the drug; 502(f) (1)—the labeling of the articles failed to bear adequate directions for use; 502(i)—the *meprobamate tablets* were (2) an imitation of another drug, namely, Miltown, and (3) were offered for sale under the name of another drug, namely, Miltown; and 503(b) (4)—the labeling of the articles failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; and 505(a)—the *meprobamate tablets* were a new drug, and an application filed pursuant to the law was not effective with respect to the drug.

PLEA: Guilty.

DISPOSITION: 5-22-59. \$1,800 fine and probation for 5 years.

5706. Vitamin B₁₂ injection. (F.D.C. No. 39431. S. No. 52-010 M.)

QUANTITY: 52 vials at Brooklyn, N.Y.

SHIPPED: 5-21-56, from Chicago, Ill., by Medical Chemicals Corp.

LABEL IN PART: (Vial) "10 cc Sterile Multiple Dose Vial Injection Cyanocobalamin U.S.P. XV Vitamin B₁₂ U.S.P. Crystalline 1000 mcg/cc in Isotonic Normal Saline Solution with 1½% of Benzyl Alcohol-Intramuscular Contains no crude cyanocobalamin."

RESULTS OF INVESTIGATION: Examination showed that each cubic centimeter of the article contained 1 milligram (=1,000 mcg.) of cyanocobalamin (vitamin B₁₂), 8.77 milligrams of sodium chloride, and 0.98 milligram of unidentified dissolved material.

LIBELED: 8-22-56, E. Dist. N.Y.

CHARGE: 501(b)—when shipped, the quality and purity of the article fell below the standard for *cyanocobalamin injection* set forth in the United States Pharmacopeia since it contained, in each cubic centimeter, dissolved material which was not permitted by the standard as an ingredient of *cyanocobalamin injection*; and 505(a)—the article, because of the presence of unidentified dissolved material, was a new drug within the meaning of 505(b), and an application filed pursuant to the law was not effective.

DISPOSITION: Medical Chemicals Corp., claimant, filed an answer denying that the article was a new drug or was adulterated as charged in the libel. The Government filed written interrogatories which the claimant answered in part and objected to in part. Thereafter, the parties having stipulated and agreed on the interrogatories to which answers should be made, the court, on 6-10-57, ordered such interrogatories to be answered.

On 3-25-59, the claimant having represented that the value of the article under seizure was negligible, and that the standard for the article set forth in the United States Pharmacopeia had been clarified to include a specific test for solids which test was not part of the U.S.P. monograph at the time of shipment, and, having consented to the entry of a decree without admitting any of the issues of law and fact involved, judgment of condemnation was entered and the article was ordered destroyed.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS*

5707. Various drugs. (F.D.C. No. 41867. S. Nos. 14-201/5 P, 14-207/11 P, 14-213/5 P, 14-223 P, 14-226 P, 14-228 P, 14-230 P.)

QUANTITY: 10 btls. of *Triple-Sulfa No. 1 tablets*; 11 btls. of *Quinidine Sulfate capsules*; 5 btls. of *Quinine Sulfate capsules*; 14 btls. of *stilbestrol tablets*; 6 btls. of *sodium salicylate tablets*; 27 btls. of *sulfadiazine tablets*; 5 btls. of *aminophylline tablets*; 7 btls. of *methyltestosterone sublingual tablets*; 27 btls. of *De-em (dextro-amphetamine sulfate) timed capsules*; 6 btls. of *sulfathiazole tablets*; 5 100-tablet vials and 7 1,000-tablet vials of *thyroid tablets*; 7 btls. of *Neo-Histagen tablets*; 6 btls. of *Theophenyllin tablets*; 22 btls. of *Timcaps (dextro-amphetamine sulfate capsules)*; 10 btls. of *#1 (dextro-amphetamine sulfate with amobarbital) capsules*; and 15 btls. of *#2 (dextro-amphetamine sulfate with amobarbital) capsules*, at Detroit, Mich., in possession of Spartan-Rex Chemical Co.

SHIPPED: Between 1-24-57 and 4-9-58, from Philadelphia, Pa., and Norwich, N.Y.

LABEL IN PART: (Btl.) "1000 Tablets S-R Triple-Sulfa No. 1 7.5 Grains," "1000 Capsules S-R Quinidine Sulfate," "1000 Capsules S-R Quinine Sulfate,"

*See also No. 5705.